UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMER		: : :	
vs.		: : (Criminal No. 05-10102-JLT
JOHN BRUENS, ET AL.		: :	
I	Defendants.	: :	
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DEFENDANTS' JOINT MOTION IN LIMINE TO EXCLUDE A PORTION OF MARY STEWART'S MARCH 6, 2002 STATEMENT TO THE FBI

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Pursuant to Federal Rule of Evidence 802, Defendants John Bruens, Mary Stewart, Melissa Vaughn, and Marc Sirockman (collectively, "Defendants") respectfully move this Court for an order, *in limine*, to exclude the editorial comments that were inserted, under the guise of redaction, into a statement made by Stewart to the FBI on March 6, 2002 (the "Stewart Statement").

PRELIMINARY STATEMENT

In its brief dated October 17, 2006, filed in opposition to certain Defendants' motion to exclude certain statements by co-defendants, the Government set out original statements of selected FBI interview reports and the Government's proposed redactions to those statements. See United States' Consolidated Opposition to the Defendants Stewart and Sirockman's Motions for Separate Trials; and Defendants Bruens and Vaughn's Motion to Preclude Admission of Mary Stewart's Statements ("Consolidated Opposition") at 6-9. One such statement related to an FBI interview of Stewart on March 6, 2002. The Original and Redacted versions, taken from page 7 of the Government's Consolidated Opposition, are as follows:

ORIGINAL STATEMENT

REDACTED STATEMENT

PAGES 6-7: STEWART was requested to review and explain the following portion of an E-mail message [footnote omitted]:

[1.] "Voicemail sent by MELISSA VAUGHN Wednesday, March 3, 1999 regarding JOHN BRUENS offer to pay for certain high writing MDs flight and hotel in Cannes, France in April to attend an HIV Nutrition/Wasting program in exchange for 30 patient Rxs during our 6 day sales blitz."

The statements on pages 6-7 of the Memorandum of Interview, as follows:

STEWART remembers this incident [i.e., the offer to pay for high prescribing physicians' flight and hotel in Cannes, France in April in exchange for 30 patient RXs during the 6 day sales blitz] and called it [someone's] 'momentary lapse of judgement. STEWART stated, the real intention was not to trade business for a trip to France. According to STEWART, MELISSA VAUGHN got upset

[2.] -- "STEWART remembers this incident and called it a 'momentary lapse of judgement by JOHN BRUENS. STEWART stated, the real intention was not to trade business for a trip to France. According to STEWART, VAUGHN got upset over this whole idea. Even though STEWART did not travel on this trip, she was aware that ALEXIS CORAZON, M.D., had traveled to France. STEWART added, that ALEXIS CORAZON, M.D. was the only physician to accept this offer from SERONO.

over this whole idea. Even though STEWART did not travel on this trip, she was aware that ALEXIS CORAZON, M.D., had traveled to France. STEWART added, that ALEXIS CORAZON, M.D. was the only physician to accept this offer from SERONO.

Id. at 7.

Paragraph 1 in the left-side column, above, contrary to the FBI agent's representation to Ms. Stewart, was not a "portion of an E-mail message". Rather, it was an editorial comment made by Kim Jackson (the "Jackson Comment"), which Jackson added as a preface to what has been identified as her transcription of the voicemail message. See Grand Jury Testimony of Kimberly Jackson on Dec. 9, 2003 at 80, attached hereto as Exhibit A ("That's my typed note.... I'm telling that it's a voicemail sent by Melissa Vaughn..."). The FBI interview memo of the Stewart Interview is attached hereto as Exhibit B. The purported voicemail transcription, with the Jackson Comment, is attached hereto as Exhibit C.

In the oral argument before this Court on January 16, 2007, the parties focused only on paragraph 2, above, specifically the "momentary lapse of judgement" portion of the Stewart Statement. The Court ruled that that portion was an admission by Stewart and that it was admissible in evidence subject only to Bruens' name being deleted and the term "another individual" substituted. See January 16, 2007 Order, attached hereto as Exhibit D at 2. There was no discussion in Court on the admissibility of Paragraph 1 of the Original Statement. Nor

¹ The Government acknowledged that the FBI agent misrepresented the nature of the Jackson Comment to Stewart. See Consolidated Opposition at 7, n. 2.

was there any discussion of what appears in the Redacted Statement column as a paraphrase of the Jackson Comment; namely,

> STEWART remembers this incident [i.e., the offer to pay for high prescribing physicians' flight and hotel in Cannes, France in April in exchange for 30 patient RXs during the 6 day sales blitz].

This issue was not argued at the January 16th hearing because the Government had represented in its brief that it would not offer the Jackson Comment in evidence. See Consolidated Opposition at 9. The Government stated in its brief:

> In the redacted form set forth above, the Government will not refer to the fact that Stewart was requested to review and explain the following portion of the following, which is Kim Jackson's typed transcription of a voice-mail message (which was incorrectly referred to as an e-mail in the Memorandum of Interview):

'Voicemail sent by Melissa Vaughn on Wednesday, March 3, 1999 regarding JOHN BRUENS offer to pay for certain high writing MDs flight and hotel in Cannes, France in April to attend an HIV Nutrition/Wasting program in exchange for 30 patient Rxs during our 6 day sales blitz.'

Id. at 9-10 (emphasis in original).

It now appears likely that, contrary to its prior representations, the Government intends to offer in evidence its paraphrase of the Jackson Comment.² This is completely improper. The Jackson Comment is inadmissible either as it appears in the FBI memorandum or as inserted into the so-called Redacted version of the Stewart Statement. It is hearsay of a third

² Before making this motion, counsel for Bruens contacted Assistant U.S. Attorney Mary Elizabeth Carmody to inquire whether the Government intends to offer the statement in evidence, despite its prior representations to the contrary. Ms. Carmody said she could not comment on the Government's position with respect to this inconsistency, and instead referred counsel to the Court's January 16th Order containing the redacted statement.

party, Kimberly Jackson, and it does not represent an admission by Stewart. It should be excluded from the Stewart Statement.

ARGUMENT

The Government improperly seeks to put before the jury inadmissible hearsay by Jackson through a purported admission by Stewart. Nothing in the text of Vaughn's voicemail indicates that anyone presented to a doctor a *quid pro quo* offer of a trip to the Cannes Conference in exchange for additional prescriptions. It is only the Jackson Comment that asserts that Vaughn's voicemail relates to "John Bruens [*sic*] offer to pay for certain high writing MDs [*sic*] flight and hotel in Cannes, France . . . in exchange for 30 patient RXs during our 6 day sales blitz." This out-of-court testimonial statement by Jackson is inadmissible hearsay for which there is no exception under the Rules. See Fed. R. Evid. 802. But by inserting the Jackson Comment into the text of the Stewart Statement, which the Government intends to offer against Stewart at trial, the Government is attempting to get this inadmissible hearsay into evidence through the back door.

Typically, redactions such as the one at issue here, made pursuant to <u>Bruton</u> and its progeny, remove from a co-defendant's statement any identifying references to another co-defendant. This Circuit generally requires that references to a co-defendant be replaced by "neutral references, using terms such as 'other individuals' or 'another person'." <u>United States v. Vega Molina</u>, 407 F.3d 511, 519 (1st Cir. 2005). The redacted version of the Stewart Statement accepted by the Court substitutes "another individual's" in place of Bruens' name, in an effort to comply with the requirements of <u>Vega Molina</u>. (<u>See Ex. D at 2</u>.) Defendants respectfully reiterate their objection for the reasons given at oral argument.

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The insertion of the Jackson Comment into the Stewart Statement, however, does not even purport to replace an identifying reference to another co-defendant. Rather, the Government simply lifts the words from the out-of-court hearsay of Kimberly Jackson – which incorporates the Government's entire theory of the case – and inserts them into the Stewart Statement.

By offering the Stewart Statement in its altered form, or testimony consistent with these alterations, the Government seeks to introduce Jackson's conclusory hearsay by pretending it is an admission by Stewart. By putting the Jackson Comment into Stewart's mouth by means of an FBI misrepresentation that this was an e-mail that Stewart presumably had received, the Government improperly suggests that when Stewart referred to the "Cannes, France program" – which was nothing more than paying expenses of certain doctors to attend an international HIV conference – she was admitting participation in an alleged conspiracy to send doctors to Cannes "in exchange for 30 patient Rxs" (Ex. C). No such admission is made in Vaughn's voicemail itself or in Stewart's interview. The insertion of this hearsay into the "redacted" statement by Stewart is wholly improper and should not be permitted.

CONCLUSION

Because the Redacted version of the Stewart Statement contains inadmissible hearsay by another witness, the Redacted statement – and any testimony consistent with this version of the statement – is inadmissible pursuant to Rule 802. Accordingly, Defendants respectfully move this Court to exclude it from evidence.

Respectfully submitted,

JOHN BRUENS, MARY STEWART, MELISSA VAUGHN, and MARC SIROCKMAN by their undersigned attorneys:

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Counsel for Marc Sirockman

Dated: March 22, 2007

CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing motion was filed electronically in compliance with ECF procedures on this 22nd day of March 2007.

/s/ Patricia C. Fratto

EXHIBIT A

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1	Boston that you had the, received the voice mail from
2	Melissa Vaughn?
3	A It would have been on that note, the transcription
4	of that voice mail. It wasn't handwritten. It was typed.
5	(Pause.)
6	MS. CARMODY: I'm sorry. I apologize for that
7	delay.
8	MS. MILLS: This was previously marked as
9	MS. CARMODY: Previously marked as Grand Jury
10	Exhibit
11	MS. MILLS:No. 22
12	MS. CARMODY:No. 22.
13	BY MS. CARMODY:
14	Q Is that the handwritten note of your voice mail
15 -	from Melissa Vaughn on March 3, 1999?
16	A That's my typed note, and that's my handwriting on
17	the bottom.
18	Q Okay. Could you read it for the grand jurors,
19	please?
20	A The whole thing?
21	Q Yes.
22	A Voice mail, I'm telling that it's a voice mail
_ 23	sent by Melissa Vaughn on Wednesday, March 3, 1999,
24	regarding John Bruens' offer to pay for certain high writing
25	physicians' flights and hotel in Cannes, France, in April to

EXHIBIT B

FEDERAL BUREAU OF INVESTIGATION

Date of transcription 03/07/2002

MARY KATHLEEN STEWART, date of birth November 7, 1961, , residing at Social Security Number , telephone number apprised to the purpose and identities of the interviewing agents.

STEWART provided the following information:

A bachelor's degree in marketing was obtained by STEWART from NORTHEASTERN UNIVERSITY, located in Boston, Massachusetts. While attending NORTHEASTERN UNIVERSITY, STEWART participated in the Co-Op Education Program and was employed at BRISTOL-MEYERS. This experience influenced STEWART to pursue employment with a pharmaceutical firm. During 1997, STEWART attended a two week executive management program at BABSON COLLEGE, located in Wellesley, Massachusetts. Currently, STEWART owns her own consulting firm, FENG SHUI BOSTON, INC., P.O. Box-368, Pembroke, Massachusetts, telephone number 781-294-7348.

In November 1991, STEWART commenced employment with SERONO LABORATORIES (SERONO) in California and held the position of Senior District Sales Manager. In March, 1994, STEWART moved to the New England region to assist with marketing SERONO's drug Saizen. In 1995, STEWART was re-assigned to assist with SERONO's drug, Serostim. While located with SERONO in the New England region, STEWART held the positions of Regional Director of Sales and then later, Vice President of Sales. In June, 2000, STEWART accepted a severance package from SERONO after being passed over for the position of Executive Vice President, which was granted to JAY MOHR.

A "couple of years" after Serostim had received approval from the FDA (U.S. Food and Drug Administration), STEWART recalled hearing that the clinical data submitted to the FDA was "incorrect." Also, in 2000, after STEWART had departed SERONO, she again heard "rumors" that the clinical data submitted by SERONO to the FDA was not correct. STEWART stated, she would not have known if the data to FDA had been "manipulated." When asked to explain these rumors that she had heard, STEWART did not respond. STEWART added, these "rumors" may have been the end product of people being angry with SERONO.

Investigation o	03/06/02	at	Pembroke,	MA		
File # 2092	A-BS-87603-302				Date dictated	03/07/02
SA	CATHY PLESHA/CP KIMBERLY VAGOS				· · · · · · · · · · · · · · · · · · ·	
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This document contains neither recommendations nor conclusions of the FBI. It is the property of the FBI and is loaned to your agency; it and its contents are not to be distributed outside your agency.

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After the review of a document entitled, "FDA, Talk Paper, FDA Approves Drug For AIDS-Wasting," dated August 23, 1996, STEWART indicated, that this document improved her memory about the drug, Serostim. STEWART recalled, initially the FDA rejected a full approval for Serostim, before granting the drug an accelerated approval. Because the FDA granted an accelerated approval, SERGY O would have to conduct additional clinical trials to further evaluate Serostim. STEWART stated, she was aware that there was a delay in these clinical trials, but she did not know the reason for the delay.

For this time period, STEWART identified TOM LANG and MARLENE BOOTH, as the individuals, who were responsible for SERONO's compliance with FDA regulations. STEWART noted, that TOM LANG is currently the President of SERONO. STEWART identified in sequential order the following as having held the position of Medical Director at SERONO: HAL LANDY, M.D.; BOB KAUFMAN, M.D.; and JOHN SULLIVAN BULEAUX (phonetic). NORMA MUURAHAINEN, M.D., Ph.D., was identified as the current Medical Director.

After the review of a memorandum from HISHAM SAMRA, President of SERONO to JEFF GETTY and BILL THORNE, representing ACT UP Golden Gate, dated June 25, 1996, and in particular the. phrases:

> "A yearly range of \$30,000 to \$36,000 for Serostim therapy is considered reasonable by both parties."

"To a clinical trial program that addresses FDA concerns, including determination of the optimal maintenance dose."

STEWART stated, "ideally" patients would only need one course_of Serostim and that makes the "cap" of \$36,000.00 "reasonable." However, as STEWART calculated out loud, one, 12 week course of treatment would cost a patient about \$21,000.00 and anyone' who needed another course of treatment would easily exceed the \$36,000.00 "cap." According to STEWART, some physicians continuously prescribed Serostim for their patients, because once their patients were taken off the drug they would begin to lose weight.

According to STEWART, the SEROCARE/NORD Program was an "umbrella" for patients, who could not afford Serostim. After the review of a document entitled, "What The Treatment Continuation Program Offers You, " STEWART stated, that patients were to receive

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Serostim "free" after an amount of \$36,000.00 had been paid. STEWART added, that there more stringent requirements for patients to qualify for the SEROCARE/NORD Program in comparison to other health plans. STEWART stated, this was because there was not enough of Serostim for everyone in the program. According to STEWART, only so much Serostim was allotted to the SEROCARE/NORD Program at any given time and this caused a waiting list or back log of patients for the drug. Reportedly, physicians became frustrated when their patients had to wait for the drug. STEWART noted, it was a difficult decision to decide, who needed the drug, but it was based on medical necessity by SERONO's medical director. STEWART added, body builders and anti-aging clinics were very interested in Serostim, but SERONO never "targeted" the anti-aging clinics or nursing homes.

STEWART was asked to comment on the possibility, that additional clinical trials for Serostim were delayed by SERONO, because the trials would indicate that patients were being over prescribed with 6 milligrams of the drug, considering the previous trials were based on 4 milligrams of Serostim. STEWART replied, she did not know.

STEWART was asked to explain, what she did when sales representatives told her that 6 milligrams of Serostim was too strong of a dosage and patients were complaining about aching body joints. STEWART replied, she "would not be surprised," if some sales representatives did not tell physicians that the number of prescribed milligrams of Serostim should correlate to a patient's weight.

During December, 1996, the Serostim Preferred Partners Program was initiated in order to find pharmacies to dispense. Serostim. After the review of a document entitled, "Serostim Preferred Partners, Serono" which listed twelve different pharmacies, STEWART stated, that this appeared to be an "old list," probably from the time period of when Serostim was in the TIND (Treatment Investigational New Drug) status for FDA approval. At some point, STEWART estimated, that there were 20 to 30 pharmacies which participated in the Serostim Preferred Partners Program. STEWART could not recall if, STADTLANDERS was the original pharmacy to dispense Serostim. STEWART stated, that she assisted with devising the Sterostim Preferred Partners Program, because SERONO needed reimbursement for the drug and initial attempts internally by SERONO to develop a reimbursement program had failed. According to STEWART, SERONO eventually discontinued this program in favor of

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distribution by wholesalers, because the smaller pharmacies could not afford to stock Serostim, due to its high cost.

Pharmacies had to fulfill certain criteria in order to become a Serostim Preferred Partner. STEWART recalled, that there was a document listing this criteria, such as, the pharmacies had to have an expertise in treating individuals which were identified as being HIV positive, have a reimbursement expertise and ability to ship the drug, as well as, have supplies available. Initially, the criteria to identify these pharmacies did not include the dollar amount of Serostim dispensed, because there was no payment history for the drug. STEWART identified, California and then New York, as the first two states to reimburse on Serostim.

The following five individuals were identified by STEWART as being involved with the Serostim Preferred Partner Program: ELLEN FRANKS, who was STEWART's boss; CINDY BELL, who had oversight of marketing; JOHN HAUSS (phonetic), who handled the contracts and , RICHARD AZULAY, who was involved with reimbursement.

STEWART stated, that the pharmacies participating in the Serostim Preferred Partners Program received a price discount from SERONO on Serostim. Price discounts were granted because these pharmacies would track the milligram amounts of Serostim dispensed. The bonuses paid by SERONO to its sales representatives were based upon this data. STEWART stated, she did not know, if these price discounts were passed onto MEDICAID, MEDICARE, CHAMPUS or the VETERANS AFFAIRS health benefit programs.

ELLEN FRANKS, as Executive Manager, had oversight of the Serostim Program, to include marketing and reimbursement. STEWART stated, that she was not certain, if FRANKS resigned or was "fired" by SERONO. STEWART believes, that ED PARRA, who was charge of the "trade group," could possibly have knowledge about price discounting. PARRA is currently residing in California. Another individual, whom STEWART believes may have information regarding price discounting is RICHARD AZULAY, who is still employed at SERONO.

As for the reporting of false data by the pharmacies, STEWART stated, she was unaware of any such activities. STEWART recalled, that there was a "gap" one time when the reported amount of Serostim dispensed was larger than the amount of drug manufactured. According to STEWART, this incident was never explained to her, but she thought it might have been a

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"distribution problem." STEWART added, that the data reporting by the pharmacies was "never exact."

After the review of a document entitled, "Serostim Pharmacy Data Collection Administrative Fee Agreement," STEWART stated, she was familiar with TDI Pharmacy located in Pittsburgh, Pennsylvania, which sold large amounts of Serostim in several states. STEWART never met the owner of TDI Pharmacy, TONY GREJDA, but he was described by some of SERONO's marketing personnel to her as "obnoxious and pushy." STEWART recalled, that she received many complaints about GREJDA, however, when requested to elaborate she did not provide any detail.

STEWART was requested to review a document entitled, "Serostim Preferred Partner Program, Background Information," and in particular the following phrase:

"MEDICAID guidelines prohibit manufactures from providing incentives or inducements to distributors for products that are used in a MEDICAID population. Serostim is approximately 75% MEDICAID. The SERONO Legal Team has advised the discontinuation of the Preferred Partner Program agreement immediately."

STEWART stated, that "incentives and inducements" referred to the price discount pharmacies were given by SERONO for reporting the number of milligrams of Serostim dispensed. According to STEWART, the MEDICAID population was "targeted" by SERONO, because largely, the majority of HIV patients are on MEDICAID.

After the review of a document entitled, "Serostim Preferred Partner Program, Preferred Provider Impact," STEWART stated, she did not know the meaning of the phrase, "Loss of chargeback money (3.75% on purchases)." STEWART believes, that RICHARD AZULAY or JEFF HART would be able to explain this phrase. STEWART indicated, that she did not know KEVIN CAST, because he arrived at SERONO after—she had departed the company.

While STEWART was employed at SERONO, the following individuals were identified as having the responsibility of assuring compliance with MEDICAID guidelines: ED PARRA, ELLEN FRANKS and RICHARD AZULAY. After STEWART departed SERONO, ISABELLE STILLGER headed this area under the direction of JAY MOHR. According to STEWART, STILLGER resigned from SERONO to spend more time with her children. JAY MOHR, who resides in Scituate,

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Massachusetts, departed SERONO within the last six months for a position with another pharmaceutical firm in Cambridge, Massachusetts.

When JEFFREY HART, was Vice President of Strategic Business Intelligence, he had oversight of data and reported this information to SERONO's management. Currently HART is assigned to Customer Service and STEWART added, "surprisingly" he is still employed at SERONO. KATHLEEN OGAR was identified as working under the supervision of HART or MELANIE WILKINS.

Initially, STEWART stated, that she could not recall the name, ABDULLAH BAAJ. STEWART believes, that ABDULLAH BAAJ was not involved with the Serostim Preferred Partners Program, but was possibly in charge of the Clinical Science Liaison Program. STEWART had the impression that ABDULLAH BAAJ held a Ph.D. degree or had a background with some type of medical training. According to STEWART, because SERONO did not like the "management style" of ABDULLAH BAAJ, he was assigned 2 or 3 sales accounts to handle for SERONO within Boston, Massachusetts, to "keep him busy."

After a review of the document entitled, "Serostim Preferred Partner Program, Reimbursement Examples," STEWART stated, that AWP refers to Average Wholesale Price, WAC refers to Wholesale Acquisition Costs and COT refers to Cost of Treatment. STEWART believes, "AWP -5%" may refer to a discount, but she was not certain.

AWP was identified by STEWART as not being the "real price," but an inflated price and this is done by everyone within the industry. STEWART described AWP as a built in "cushion" to create a pricing gap, but she could not recall the pricing for Serostim. Additionally, STEWART stated, she did not know, if SERONO reported to the Government an overly inflated AWP or if the discount price granted to some pharmacies was factored into the AWP pricing.

STEWART was requested to review and explain the following portion of an E-mail message:

"Voicemail sent by MELISSA VAUGHN Wednesday, March 3, 1999 regarding JOHN BRUENS offer to pay for certain high writing MDs flight and hotel in Cannes, France in April to attend an HIV Nutrition/Wasting program in exchange for 30 patient RXs during our 6 day sales blitz."

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STEWART remembers this incident and called it a "momentary lapse of judgement" by JOHN BRUENS. STEWART stated, the real intention was not to trade business for a trip to France. According to STEWART, VAUGHN got "upset" over this whole idea. Even though STEWART did not travel on this trip, she was aware that ALEXIS CORAZON M.D., had traveled to France. STEWART added, that ALEXIS CORAZON, M.D., was the only physician to accept this offer from SERONO. Currently, VAUGHN is working for a company in Colorado, and BRUENS is employed by another company in California. SUE WOMBLE, was an Administrative Assistant to BRUENS, who had oversight of the Marketing Department. Currently, SUE WOMBLE is located on the south shore region of Massachusetts.

STEWART was requested to review a memorandum from SUE -WOMBLE, Metabolic & Immune Therapy to HOWARD GROSSMAN, M.D., dated March 31, 199(9), and in particular the following phrase:

"Included with this invitation is an offer of a \$4,000 % grant for the purchase of airline tickets to Cannes. If you decide you would like us to make your flight arrangements for you, in lieu of the grant, we will purchase on your behalf one business class round trip ticket."

STEWART stated, obviously, she was wrong and other physicians had traveled to France.

According to STEWART, SERONO gave physicians "more attention" if they wrote numerous prescriptions for Serostim. STEWART described "attention" as buying physicians dinners, or "attention from SERONO management, "-but not a monetary compensation.

STEWART stated, that SERONO received "hundreds" bf requests from physicians for money; and it was not from the "high writing" physicians as one would suspect. When requested to identify specific physicians, who made such requests, STEWART did not respond. It seemed to STEWART that physicians always wanted "something for nothing." It was quite common, according to STEWART, for physicians to request "educational grants" which paid for their air travel to attend HIV conferences sponsored by SERONO. STEWART stated, she was not certain if these physicians actually ever attended the conferences.

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The SERNONAIDS Program collects data on HIV patients and AIDS wasting patients. STEWART advised, that physicians submit data regarding their patients to SERONO, and they are in turn paid \$250.00 or \$300.00 for each completed form. SERONO made payments to the physicians on possibly a quarterly or some other pre-determined basis. Physicians submitted the forms to CINDY MAGAL and ABDULLAH BAAJ. The Clinical Science Liaison Program was responsible for recruiting physicians, and they did so by sometimes identifying physicians through published studies. According to STEWART, all physicians participating in the program had to sign a contract agreement with SERONO. STEWART was not certain, if the physicians also received a fee for BIA (Bioelectrical Impedance Analysis) testing. Some physicians, STEWART believes, were "lent" BIA machines in order to perform BIA testing. ROSS PETTIT, was identified by STEWART as the Director of Medical Services, with oversight of this program. STEWART identified CINDY BELL as a close friend, who would know more facts about the SERONAIDS Program. STEWART added, CINDY BELL told her, she anticipates in about 2 weeks, to be "fired" by SERONO.

STEWART identified NORMA MUURAHAINEN, M.D., Ph.D., as SERONO's current Medical Director and BOB KAUFFMAN, M.D., as the former Medical Director, and both of these individuals had oversight of the SERONAIDS Program.

The purpose of BIA testing is to determine muscle mass and to track muscle mass over a time period. According to STEWART, sometimes sales representatives of SERONO performed BIA testing on patients by themselves and sometimes with the assistance of medical personnel within the physicians' offices. Typically, a sales representative would give a print-out of a patient's BIA test results to the physician, who reviewed it and decided, if the patient needed to be prescribed Serostim. STEWART stated, physicians would enter the BIA test results into the patient's medical record and not the sales representative, even though they may have actually performed the testing. In some instances, STEWART advised, medical personnel within the physicians' offices would ask the sales representatives to perform the BIA testing, because they were too busy or just did not want to do the testing. STEWART felt some medical personnel "pushed off" onto the sales representatives.

STEWART believes, there was no reimbursement by insurance programs for BIA testing. Also, STEWART is not aware of sales

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representatives telling physicians to bill for BIA testing, even when the testing was not performed by the physicians.

STEWART stated, "it was under" her leadership that some sales representatives, had reviewed patient medical records within physicians' offices in order to identify potential Serostim patients. According to STEWART, sales representatives were instructed not to do this, because it was not part of SERONO's sales plan.

After a review of the document entitled, Serostim Preferred Partner Program, Preferred Provider Impact," and in particular the phrase:

"Providers will not be held accountable to SERONO's SOP for BIAs etc..."

STEWART believes, that this refers to the pharmacies that performed BIA testing.

JOHN BRUENS and SCOTT LUNDIE (phonetic) from the Marketing Department were identified by STEWART as having had "control" over the BIA machines. "STEWART recalled, that SCOTT LUNDIE, whom she described as "computer literate," once changed the computer programs of the BIA machines and the sales representatives "revolted." When STEWART was requested for specifics regarding this "modification," she did not respond.

STEWART did not know why or the identity of the individual, who selected CPT codes 93720, 93721 and 93722 for BIA testing. After a review of the CPT descriptions for the previous mentioned codes, STEWART stated, that these codes do not seem appropriate for BIA testing, because of the reference to respiratory. STEWART believes, RICHARD AZULAY, who has oversight of insurance reimbursement may be able to answer this question.

A document entitled, "BIA Fluid - Nutrition Assessment" was identified by STEWART as the form to record patient data measurements from BIA testing. In BIA testing, electrodes are placed on the patient's body which generates data. The sales representative would then load this data into the physician's computer. STEWART stated, "adjusting" or "fudging" data was not condoned by SERONO. According to STEWART, if any data was changed, such as the phase angle, the data would not be accurate.

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Continuation of FD-302 of MARY KATHLEEN STEWART

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After the review of a document entitled, Metabolic & Immune Therapy, MARY STEWART, Vice President, Sales," STEWART stated, that a "couple" of sales representatives "stood out in her mind." However, STEWART would not identify these individuals.

STEWART was requested to review a document entitled, "Feedback on MARC SIROCKMAN." Upon review STEWART stated, she was the one who had requested that MARC SIROCKMAN's employment with SERONO be terminated because of his "business practices." MARC SIROCKMAN worked in New Jersey and was a close, personal friend to ALEXIS CORAZON, M.D. According to STEWART, there were "rumors" that MARC SIROCKMAN had "manipulated" grant money without authorization. When MARC SIROCKMAN was approached by SERONO, he denied all allegations. STEWART described MARC SIROCKMAN as being "aggressive, too pushy" and "a cowboy, on his own; doing his stuff." Recently, STEWART advised, she had been contacted by MARC SIROCKMAN, who requested she provide an employment reference for him. STEWART added, no one has contacted her to date.

STEWART offered the following information regarding various SERONO sales representatives:

RAY HUDGENS was located in Florida, and STEWART had not heard his reported claim, if the phase angle of BIA test results were changed to the number 7, rather than the number 6, more patients would need Serostim. STEWART remembers RAY HUDGENS as a "consistent performer," who worked for either MELISSA VAUGHN or DAVE SAWIN, who were respectively Executive Area Directors.

ANGELO SAVERINO was located in Bronx, New York, and STEWART recalled nothing megative about SAVERINO, she described him as "quiet, low profile, not great sales and not a consistent performer." ANGELO SAVERINO was under the direction of ADAM STUPAK, who often had sales incentives for his sales representatives.

TODD SULLIVAN was located in New Jersey, and STEWART described him as being "very aggressive, someone she never trusted and sleazy." STEWART stated, she had no specific reasons for not trusting TODD SULLIVAN.

TODD MIKOLAJCZYK was also located in New Jersey and STEWART described him as an "OK guy."

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PHIL BLACK was located in California, and STEWART was "shocked" when she heard he had been terminated by SERONO for doing something wrong regarding a hospital. STEWART stated, she could not recall the details regarding PHIL BLACK.

According to STEWART, there is so much jealousy among sales representatives that this often made it difficult to discriminate between truth and jealousy. STEWART offered the opinion that MELISSA VAUGHN, DAVE SAWIN and VANCE LNU (Last Name Unknown) were "sacrificial lambs," who were terminated by SERONO.

STEWART stated, she had "only heard" about ABDULLAH BAAJ's "open label study" of prescribing Serostim in the treatment of lipodystrophy, and that the study had to be discontinued. After the review of a document entitled, "An Open Label Study to Determine the Effect of Low Dose Growth Hormone on Visceral Fat Accumulation in HIV-Infected Patients," STEWART stated, that this document had to be an early draft of the final paper. After the review of a document entitled, "SERONO, Notice of Compliance," STEWART stated, that this was for the recall of promotional literature. Since ABDULLAH BAAJ Kad only been given 2 or 3 accounts in Boston, Massachusetts, STEWART identified, CHRISTINE DRISCOLL and TODD WILLINDER, both sales representatives, as individuals who would have knowledge regarding ABDULLAH BAAJ's lipodystrophy study. STEWART believes, ABDULLAH BAAJ's "open label study" was limited to these 2 or 3 accounts in Boston. STEWART was not certain, if any information from this study was ever entered into the SERONAIDS Program nor the reason that ABDULLAH BAAJ departed SERONO. CHRISTINE DRISCOLL was identified as still employed at SERONO, but someone who has been talking for sometime while of leaving SERONO.

As for the drug, Serostim, STEWART stated, she "believes" that the drug has "saved" many peoples' lives. Also, STEWART told of participating in telephone hot-line calls regarding AIDS and that she heard much "positive feed-back" from patients regarding Serostim.

Before STEWART departed SERONO, she was put on an "International Team" for Serostim and traveled almost on a weekly basis between Massachusetts and Switzerland. According to STEWART, she believes this assignment was given to her in consolation for being passed over for the position of Executive Vice President, which was granted to JAY MOHR. Eventually, STEWART stated, all the

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traveling made it too difficult for her, and she decided to resign her position with SERONO.

EXHIBIT C

Voicemail sent by Melissa Vaughn Wednesday, March 3, 1999 regarding John Bruens offer to pay for certain high writing MDs flight and hotel in Cannes, France in April to attend an HIV Nutrition/Wasting program in exchange for 30 patient Rxs during our 6 day sales blitz

"Hey guys - This message is going to the RDs and I'm going to copy Mary Stewart and John Bruens on this. I just had a couple of very sobering phone calls from two of my CCs who presented the Cannes, France program and I can tell you that they presented it in one of the best ways we could possibly present it. They presented it to doctors with whom they have excellent relationships and rapport, who are also top doctors and who had the potential to bring in 30 scrips for the next week or so, and who also would have been perfect for speaking, and so we had everything laid out perfectly – it was the perfect scenario.

"These individuals each called me literally within five minutes of each other and could not express to me the horrible experience they went through and the things that were said to them by their doctors about this program: that it was unethical, that this is the very thing that the FDA looks for, that our drug is too good, our reputation is too good, our clinical consultants work too hard and the reputation is too positive to be stooping to such levels – why is Serono doing this? It just wasn't good – it was not good. I can't express it enough. I just wanted to let you know that we will not be doing this program in the south. We will get enough. It just wanted to let you know that we will not be doing this program in the south. We will get enough we will do what we need to do, but we won't go to desperate means that will compromise who we are as a company and who we are as individuals because I'm very proud of who we are and our product and essentially everything we represent as a company and as a product. I thought I'd pass this on to you just to give you some feedback and let you make your own decisions, but it was important enough for me to send it to the group."

Ray Hudgens and Adam Whitehurst were the CCs who asked the physicians. One MD was Dr. Piperato.

EXHIBIT D

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,

*

Criminal No. 05-10102-JLT

JOHN BRUENS, MARY STEWART, MELISSA VAUGHN, and MARC SIROCKMAN,

*

Defendants.

ORDER

January 16, 2007

TAURO, J.

v.

After a Motion Hearing held on January 16, 2007, this court hereby orders that:

- 1. Defendants' <u>Joint MOTION to Strike the Surplusage in the Indictment Pursuant to Rule 7(d)</u> [#62] is DENIED.
- Defendants' <u>Joint MOTION to Sever Counts as to John Bruens</u>, <u>Mary Stewart</u>,
 <u>Melissa Vaughn</u>, <u>Marc Sirockman</u>.[#66] is DENIED.
- 3. Defendant Sirockman's <u>MOTION to Sever Defendant Sirockman from Trial</u> [#61] is DENIED.
- 4. Defendant Mary Stewart's Motion for Separate Trial [#70] is DENIED.
- Defendant Bruens's and Defendant Vaughn's <u>Joint MOTION to Preclude</u>
 <u>Statements Made by Co-Defendant Mary Stewart</u> [#68] is DENIED.
- 6. In accordance with the First Circuit Court of Appeals's decision in Vega Molina, 1

¹ United States v. Vega Molina, 407 F.3d 511 (1st Cir. 2005).

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Marc Sirockman's December 13, 2001, statement and Mary Stewart's March 6, 2002, statement shall be redacted as proposed by the Government in its Consolidated Opposition [#74], with the following modifications.

Marc Sirockman's December 13, 2001, statement to investigators of the State of New Jersey:

Only doctors who exceeded their normal prescription rate by a certain percentage were considered for attendance. Sirockman did not know the specific figure but thought that it might have been ten percent. . . . [Other individuals] selected the doctors who attended "Con France." Serono paid for all expenses (air fare, hotel, and meals), and also provided the doctors with spending money.

Mary Stewart's March 6, 2002, statement to the FBI:

STEWART remembers this incident [i.e., the offer to pay for certain high writing physicians' flight and hotel in Cannes, France in April to attend an HIV Nutrition/Wasting program in exchange for 30 patient RXs during the 6 day sales blitz] and called it [another individual's] 'momentary lapse of judgement.' Stewart stated, the real intention was not to trade business for a trip to France. According to STEWART, MELISSA VAUGHN got upset over this whole idea. Even though STEWART did not travel on this trip, she was aware that ALEXIS CORAZON, M.D., had traveled to France. STEWART added, that ALEXIS CORAZON, M.D. was the only physician to accept this offer from SERONO.

This court will not redact Mary Stewart's statement about Alexis Corazon because that statement alone does not incriminate other co-defendants.²

² See id. at 520 (citing <u>Richardson v. Marsh</u>, 481 U.S. 200, 208, (1987)) ("Statements that are incriminating only when linked to other evidence in the case do not trigger application of Bruton's preclusionary rule.").

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7. A trial order will issue.

IT IS SO ORDERED.

/s/ Joseph L. Tauro
United States District Judge